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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,540	02/25/2002	George C. Prendergast	WST89AUSA	1467
270	7590	03/19/2004	EXAMINER	
HOWSON AND HOWSON ONE SPRING HOUSE CORPORATION CENTER BOX 457 321 NORRISTOWN ROAD SPRING HOUSE, PA 19477			SAIDHA, TEKCHAND	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,540

Applicant(s)

PRENDERGAST ET AL.

Examiner

Tekchand Saidha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 28-56 is/are pending in the application.
4a) Of the above claim(s) 33-51 and 53-56 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 28-32 and 52 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Preliminary Amendment received February 25, 2002 has been entered. Claims 2-27 have been canceled and new claims 28-56 have been added. Claims 1 and 28-56 are pending.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 28-32 & 52, drawn to Bin2 polypeptide and composition thereof.

Group II, claim(s) 33-39, drawn to nucleic acid encoding Bin2 polypeptide, vector & host cell.

Group III, claim(s) 40-41, 44 & 54, drawn to diagnostic reagent and method of diagnosing cancer using DNA encoding Bin 2.

Group IV, claim(s) 42-43 & 49, drawn to drawn to diagnostic reagent and method of diagnosing cancer using Bin 2 polypeptide.

Group V, claim(s) 45-47, drawn to antibody to Bin2 polypeptide.

Group VI, claim(s) 48, 50-51 & 53, drawn to diagnostic reagent and method of diagnosing cancer using antibody to Bin2.

Group VII, claim(s) 54, drawn to method of detecting inappropriate expression of Box-dependent myc-interacting peptide-2 (bin2).

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Group VIII, claim(s) 55-56, drawn to method of identifying compound(s) that specifically binds to or inhibits binding to Bin2 polypeptide.

4. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I has a special technical feature of the Bin2 polypeptide of SEQ ID NO : 2, which Groups II-VIII do not share; Group II has a special technical feature of the Bin2 nucleic acid sequence of SEQ ID NO : 1, which Groups III and IV-VIII do not share; Group III has a special technical feature of reagents and diagnostic for cancer detection using the DNA encoding Bin2 polypeptide of SEQ ID NO : 2, which Groups I-II and IV-VIII do not share; Group IV has a special technical feature of reagent and diagnostic for cancer detection using the Bin2 polypeptide of SEQ ID NO : 2, which Groups I-III & V-VIII do not share; Group V has a special technical feature of antibody to Bin2 polypeptide, which Groups I-IV and VI-VIII do not share; Group VI has a special technical feature reagent and diagnostic using the antibody to Bin2 polypeptide, which Groups I-V and VII-VIII do not share; Group VII has a special technical feature of method of detection of inappropriate expression of BOX-dependent myc-interacting peptide-2 (Bin2), which Groups I-VI and VIII do not share; Group VIII has a special technical feature of a method for identifying compounds that bind or inhibit binding to Bin2, which Groups I-VII do not share. Thus the various groups discussed above show a lack of unity of invention.

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5. During a telephone conversation with Tracy Talbert on March 1, 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1, 28-32 & 52. Affirmation of this election must be made by applicant in replying to this Office action. Claims 33-51, 53-56 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Rejoinder

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. ***Priority***

Acknowledgment is made of applicants' claim for priority based on provisional application filed August 31, 1999.

Specification

9. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

10. **35 U.S.C. § 101**

35 U.S.C. §101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title".

Claims 1, 28-32 and 52 are rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter.

In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter. *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims 1 [and all independent claim(s)] to recite wording such as "An isolated Bin2 peptide". Claims 28-32 and 52 are included in the rejection for failing to correct the defect present in the base claim.

11. Claims 1, 28-32 & 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 28-32 & 52 recite 'Bin2', an uncommon abbreviation. The first use of an uncommon abbreviation be spelled out, which may be abbreviated subsequently.

Claim 28 (a), recite a fragment of Bin2 comprising at least 8 amino acids in length, wherein any of said fragments comprising the sequence of amino acids 23 to 35 of SEQ ID NO : 2 comprise at least 14 amino acids in length; and any fragments comprising the sequence of amino acids 138-155 of SEQ ID NO : 2 comprise at least 19 amino acids in length.

This entire recitation is indefinite and confusing regarding what is being claimed. Fragment of Bin2 is followed by – at least 8 amino acids—wherein any of the fragments; it is not clear when 'fragment becomes fragments'; and how a fragment of at least 8 amino acids would comprising residues 23-35, which would be 13 amino acid long; or residues 138-155 would be 18 amino acid long and be comprised by a 14 amino acid fragment.

The language is further complicated in claim 31 wherein the fragment off Bin2 is at least 8 amino acids in length and comprising a sequence of..... amino acids 1 to 13 of SEQ ID NO : 2. It is not clear if Applicants' intention is to claim any fragment 8 amino acids in length corresponding the amino acid residues 1 to 13 of SEQ ID NO: 2.

Rewriting the claim(s) and clearly defining the claim language will overcome this rejection.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 28, 30 rejected under 35 U.S.C. 102(e) as being anticipated by Sparks et al. [USP 6,309,820]. Sparks et al. teach a polypeptide comprising amino acid residues 23-35 and 138-155, which are 100% identical to Applicants SEQ ID NO : 2 – residues 23-35 and 138-155. 'Bin2 polypeptide' is an Applicant designated name with no specific defined function(s) associated with the polypeptide or the fragments. Therefore the claimed polypeptide(s) comprising the fragments of any length (claim 1) or that defined by the selected residues (claims 28 & 30), [see the enclosed sequence search alignments – **marked 'A' and 'B'**] is anticipated by the polypeptide(s) of the reference.

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13. Claims 1, 28, 30 and 52 rejected under 35 U.S.C. 102(b) as being anticipated by Prendergast et al. [USP 5,605,830, **IDS**, issued 2.25.97]. Prendergast et al. teach a polypeptide comprising amino acid residues 23-35 and 138-155, which are 100% identical to Applicants' SEQ ID NO : 2 – residues 23-35 and 138-155. A composition comprising the polypeptide is also taught. 'Bin2 polypeptide' is an Applicant designated name with no defined or known specific function(s) associated with the polypeptide or the fragments. Therefore the claimed polypeptide(s) comprising the fragments of any length (claim 1) or that defined by the selected residues (claims 28 & 30), [see the enclosed sequence search alignments – **marked 'A' and 'B'**] is anticipated by the polypeptide(s) of the reference.

14. Claims 1 & 28 rejected under 35 U.S.C. 102(b) as being anticipated by Prendergast et al. [USP 5,723,581, issued 3.3.98]. Prendergast et al. teach a Bin1 polypeptide comprising amino acid residues 23-35, which is 100% identical to Applicants SEQ ID NO : 2 – residues 23-35. 'Bin2 polypeptide' is an Applicant designated name with no defined or known specific function(s) associated with the polypeptide or the fragments. Therefore the claimed polypeptide(s) comprising the fragments of any length (claim 1) or that defined by the selected residues (claims 28), [see the enclosed sequence search alignments – **see page 3, result 3**] is anticipated by the polypeptide(s) of the reference.

15. Only the most relevant references which read upon the claimed fragments or residues have been cited in order to avoid repetition and to reduce the number of issues.

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16. Claims drawn to full length Bin2 SEQ ID NO : 2 or SEQ ID NO : 2, amino acid residues 1-221 with specified function will be in a better condition for allowance.

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (571) 272-0940. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group in the Technology Center is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 571 272-1600.



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March 15, 2004